MAR 2 3 2012

510(k) SUMMARY

SUBMITTED BY: BECTON, DICKINSON AND COMPANY
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CONTACT NAME: Gregory Payne

DATE PREPARED: March 15, 2012

DEVICE TRADE NAME: BD Veritor™ System for Rapid Detection of Flu A+B

DEVICE COMMON NAME: Influenza virus serological reagents

DEVICE CLASSIFICATION: 21 CFR § 866.3330

PREDICATE DEVICES: Quidel QuickVue Influenza A+B

INTENDED USE:

The BD Veritor™ System for Rapid Detection of Flu A+B is a rapid chromatographic immunoassay for the direct and qualitative detection of influenza A and B viral nucleoprotein antigens from nasopharyngeal wash/aspirates of symptomatic patients. The BD Veritor System for Rapid Detection of Flu A+B is a differentiated test, such that influenza A viral antigens can be distinguished from influenza B viral antigens from a single processed sample using a single device. The test is to be used as an aid in the diagnosis of influenza A and B viral infections. A negative test is presumptive and it is recommended that these results be confirmed by viral culture or an FDA-cleared influenza A and B molecular assay. Negative test results do not preclude influenza viral infection and should not be used as the sole basis for treatment or other patient management decisions. The test is not intended to detect influenza C antigens.

Performance characteristics for influenza A and B were established during January through March of 2011 when influenza viruses A/2009 H1N1, A/H3N2, B/Victoria lineage, and B/Yamagata lineage were the predominant influenza viruses in circulation according to the *Morbidity and Mortality Weekly Report* from the CDC entitled "Update: Influenza Activity—United States, 2010-2011 Season, and Composition of the 2011-2012 Influenza Vaccine." Performance characteristics may vary against other emerging influenza viruses.

If infection with a novel influenza virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent influenza viruses and sent to the state or local health department for testing. Virus culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.

DEVICE DESCRIPTION:

The BD Flu A+B test is a chromatographic assay to qualitatively detect influenza A and B viral antigens in samples processed from respiratory specimens. The processed specimen is added to the test device where influenza A or influenza B viral antigens bind to anti-influenza antibodies conjugated to detector particles on the A+B test strip. The antigen-conjugate complex migrates across the test strip to the reaction area and is captured by an antibody line on the membrane. Results are interpreted by the BD Veritor™ System Reader, a portable electronic device which uses a reflectance-based measurement method to evaluate the line signal intensities on the assay test strip, and applies specific algorithms to determine the presence or absence of any target analyte(s). A liquid crystal display (LCD) on the instrument communicates the results to the operator.

DEVICE COMPARISON:

The BD Veritor™ System for Rapid Detection of Flu A+B was compared to the Quidel QuickVue Influenza A+B test (k053146 and k092698).

Product Feature	BD Veritor™ System for Flu A+B	Quidel QuickVue Influenza A+B (k053146)
Intended Use	The **BD Veritor™** System for Rapid Detection of Flu A+B is a rapid chromatographic immunoassay for the direct and qualitative detection of influenza A and B viral nucleoprotein antigens from nasopharyngeal wash/aspirates of symptomatic patients. The **BD Veritor** System for Rapid Detection of Flu A+B is a differentiated test, such that influenza A viral antigens can be distinguished from influenza B viral antigens from a single processed sample using a single device. The test is to be used as an aid in the diagnosis of influenza A and B viral infections. A negative test is presumptive and it is recommended that these results be confirmed by viral culture or an FDA-cleared influenza A and B molecular assay. Negative test results do not preclude influenza viral infection and should not be used as the sole basis for treatment or other patient management decisions. The test is not intended to detect influenza C antigens. Performance characteristics for influenza A and B were established during January through March of 2011 when influenza viruses A/2009 H1N1, A/H3N2, B/Victoria lineage, and B/Yamagata lineage were the predominant influenza viruses in circulation according to the *Morbidity and Mortality Weekly Report* from the CDC entitled "Update: Influenza Activity—United States, 2010-2011 Season, and Composition of the 2011-2012 Influenza Vaccine." Performance characteristics may vary against other emerging influenza viruses. If infection with a novel influenza virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent influenza viruses and sent to the state or local health department for testing. Virus culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.	The QuickVue® Influenza A+B test allows for the rapid, qualitative detection of influenza type A and type B antigens directly from nasal swab, nasopharyngeal swab, nasal aspirate, and nasal wash specimens. The test is intended for use as an aid in the rapid differential diagnosis of acute influenza type A and type B viral infections. The test is not intended to detect influenza C antigens. Negative results should be confirmed by cell culture; they do not preclude influenza virus infection and should not be used as the sole basis for treatment or other management decisions. The test is intended for professional and laboratory use.
Specimen Types	Nasopharyngeal wash/aspirates	Nasal swab, nasopharyngeal swab, nasal wash/aspirate
Assay Technology	Immunochromatographic	Immunochromatographic

Detection Format	An opto-electronic reader determines the line intensity at each of the spatially-defined test and control line positions, interprets the results using the scoring algorithm, and reports a positive, negative, or invalid result on the LCD screen based on pre-set thresholds.	Visual determination of presence or absence of pink-to-red Test Line and the appearance of a blue Procedural Control Line on the test strip indicate the presence of influenza A and/or B antigen.
Qualitative	Yes	Yes
Total Assay Time	Approximately 10 minutes	Less than 15 minutes
Control format	• Kit Flu A+/B− dry swab procedural control • Kit Flu B+/A− dry swab procedural control • Internal positive control • Internal negative control	• Kit Flu A+ control swab • Kit Flu B+ control swab • Kit Negative control swab • Internal control lines
Detection of Flu A and B viruses	Differentiated influenza A and influenza B	Differentiated influenza A and influenza B

SUMMARY OF PERFORMANCE DATA:

Analytical Sensitivity

The limit of detection (LOD) for the BD Veritor System for Rapid Detection of Flu A+B test was established for a total of 7 influenza strains: 4 influenza A and 3 influenza B. The LOD for each strain represents the lowest concentration producing a positivity rate of approximately 95% based on testing 20 to 60 replicates.

Type	Influenza Viral Strain	Calculated LOD ($TCID_{50}$/mL)	No. Positive / Total	% Positive
A	A/Brisbane/10/2007 H3N2	7.27×10^2	57/60	95%
A	A/Brisbane/59/2007 H1N1	3.30×10^2	57/60	95%
A	A/California/7/2009 H1N1	5.00×10^3	57/60	95%
A	A/Victoria/3/75 H3N2	3.11×10^3	59/60	98.3%
B	B/Brisbane/60/2008	7.42×10^3	58/60	96.7%
B	B/Florida/4/2006	1.30×10^3	58/60	96.7%
B	B/Lee/40	4.44×10^4	20/20	100%

$TCID_{50}$/mL = 50% Tissue Culture Infectious Dose

Analytical Specificity

A panel of 52 influenza viral strains including 20 Influenza A strains and 32 Influenza B strains were evaluated in triplicate with the BD Veritor™ System for Rapid Detection of Flu A+B test. All Influenza A viruses and all Influenza B viruses were correctly detected by the test.

Cross Reactivity

A total of 51 microorganisms (36 bacteria, one yeast, and 14 viruses) were tested in triplicate with the BD Veritor™ System for Rapid Detection of Flu A+B test. None of the microorganisms tested were shown to be cross reactive with the test.

Interfering Substances

A variety of substances including whole blood, prescription medications and over-the-counter (OTC) medications, were tested with the BD Veritor™ System for Rapid Detection of Flu A+B test in triplicate at concentration levels comparable to or greater than levels that may be present in patient respiratory samples. None of the substances evaluated were shown to interfere with the performance of the test.

Media Compatibility

Ten different types of transport media commonly used for the preservation and transport of respiratory specimens were evaluated for compatibility with the BD Veritor™ System for Rapid Detection of Flu A+B test. The effects of frozen storage of transport media samples on the stability of the antigen were also evaluated in this study.

CLINICAL STUDIES
Reproducibility

The reproducibility of the BD Veritor System for Rapid Detection of Flu A+B test was evaluated at three clinical laboratory sites. The reproducibility panel was composed of 30 simulated influenza A or B samples. These included moderate positive samples, low positive samples (near the assay limit of detection), high negative samples (i.e., containing very low concentrations of virus such that positive results occur ~5% of the time) and negative samples. The results are summarized below.

Reproducibility Results – Percent of Flu A Positives				
Sample	**Site 1**	**Site 2**	**Site 3**	**Total**
High negative H1N1 A	3.3% (1/30) (0.6%,16.7%)	0.0% (0/30) (0.0%,11.3%)	0.0% (0/30) (0.0%,11.3%)	1.1% (1/90) (0.2%,6.0%)
Low positive H1N1 A	93.3% (28/30) (78.7%,98.2%)	86.7% (26/30) (70.3%,94.7%)	93.3% (28/30) (78.7%,98.2%)	91.1% (82/90) (83.4%,95.4%)
Moderate positive H1N1 A	100.0% (30/30) (88.6%,100.0%)	96.7% (29/30) (83.3%,99.4%)	100.0% (30/30) (88.6%,100.0%)	98.9% (89/90) (94.0%,99.8%)
High negative H3N2 A	16.7% (5/30) (7.3%,33.6%)	3.3% (1/30) (0.6%,16.7%)	0.0% (0/30) (0.0%,11.3%)	6.7% (6/90) (3.1%,13.8%)
Low positive H3N2 A	93.3% (28/30) (78.7%,98.2%)	86.7% (26/30) (70.3%,94.7%)	93.3% (28/30) (78.7%,98.2%)	91.1% (82/90) (83.4%,95.4%)
Moderate positive H3N2 A	100.0% (30/30) (88.6%,100.0%)	100.0% (30/30) (88.6%,100.0%)	96.7% (29/30) (83.3%,99.4%)	98.9% (89/90) (94.0%,99.8%)
Flu A Negatives	0.8% (1/120) (0.1%,4.6%)	0.0% (0/120) (0.0%,3.1%)	0.0% (0/119) (0.0%,3.1%)	0.3% (1/359) (0.0%,1.6%)

Reproducibility Results – Percent of Flu B Positives				
Sample	**Site 1**	**Site 2**	**Site 3**	**Total**
High negative B	3.3% (1/30) (0.6%,16.7%)	0.0% (0/30) (0.0%,11.3%)	0.0% (0/30) (0.0%,11.3%)	1.1% (1/90) (0.2%,6.0%)
Low positive B	90.0% (27/30) (74.4%,96.5%)	63.3% (19/30) (45.5%,78.1%)	82.8% (24/29) (65.5%,92.4%)	78.7% (70/89) (69.0%,85.9%)
Moderate positive B	96.7% (29/30) (83.3%,99.4%)	100.0% (30/30) (88.6%,100.0%)	100.0% (30/30) (88.6%,100.0%)	98.9% (89/90) (94.0%,99.8%)
Flu B Negatives	0.0% (0/210) (0%,1.8.0%)	0.0% (0/210) (0.0%,1.8%)	0.0% (0/210) (0.0%,1.8%)	0.0% (0/630) (0.0%,0.6%)

Clinical Performance

EXPECTED VALUES

The rate of positivity observed in respiratory testing will vary depending on the method of specimen collection, handling/transport system employed, detection method utilized, the time of year, age of the patient, geographic location, and most importantly, local disease prevalence. The overall prevalence observed with an FDA-cleared influenza A and B molecular assay in the U.S. during the 2010-2011 clinical study was 23.9% for influenza A and 7.5% for influenza B. At the clinical site located in Hong Kong, the prevalence observed with the same FDA-cleared influenza A and B molecular assay was 7.2% for influenza A and 3.4% for influenza B.

PERFORMANCE CHARACTERISTICS

Clinical Performance:

Performance characteristics for the **BD Veritor** System for Rapid Detection of Flu A+B test were established in multi-center clinical studies conducted at two U.S. trial sites and one Hong Kong trial site during the 2010-2011 respiratory season. A total of 1502 prospective specimens (1002 in the U.S and 500 in Hong Kong) were evaluated using the **BD Veritor** System for Rapid Detection of Flu A+B test and PCR. Five specimens were not evaluable because of data reconciliation issues, an additional 13 were excluded because of insufficient sample volume for reference method testing and 13 samples were excluded as "Result Invalid" (for an invalid rate of 0.9% [13/1484]). The prospective specimens consisted of nasopharyngeal washes and aspirates from symptomatic patients. 49% of the samples were from females and 51% from males. 56.6% were from patients less than or equal to 5 years of age. 21.9% of the patients tested were in the 6-21 year age group, 5.7% were from 22-59 years of age and 15.8% were obtained from people greater than or equal to age 60 (the patient age was not provided for 0.1% of samples).

The performance of the **BD Veritor** System for Rapid Detection of Flu A+B test was compared to an FDA-cleared Influenza A and B molecular assay (PCR).

Explanation of Terms:

PPA: Positive Percent Agreement = a / (a+c) × 100%

NPA: Negative Percent Agreement = d / (b+d) × 100%

P: Positive

N: Negative

C.I.: Confidence Interval

	Comparator Method	
New Test Method	P	N
P	a	b
N	c	d
Total	(a+c)	(b+d)

The performance is presented in Table 1 below. .

Table 1: Summary of the Performance of the BD Veritor System for Rapid Detection of Flu A+B Test Compared to PCR for All Nasopharyngeal Wash/Aspirate Specimens – All Sites

	Reference PCR		
Clinical kit: BD Flu A	P	N	Total
P	224	29	253
N	46	1172	1218
Total	270	1201	1471
Reference Method: PCR PPA: 83.0% (95% C.I. 78.0%- 87.0%) NPA: 97.6% (95% C.I. 96.6%- 98.3%)			

	Reference PCR		
Clinical kit: BD Flu B	P	N	Total
P	74	3	77
N	17	1377	1394
Total	91	1380	1471
Reference Method: PCR PPA: 81.3% (95% C.I. 72.1%- 88.0%) NPA: 99.8% (95% C.I. 99.4%- 99.9%)			

An additional 263 frozen retrospective specimens were evaluated with the **BD Veritor** System for Rapid Detection of Flu A+B test. Twelve samples were excluded because there was insufficient sample volume for reference method testing, one sample was excluded as a PCR "Unresolved" and one sample was excluded as "Result Invalid" (for an invalid rate of 0.4% [1/250]). The retrospective specimens consisted of nasopharyngeal washes and aspirates from symptomatic patients. 44.9% of the samples were from females and 55.1% from males. 87.5% were from patients less than or equal to 5 years of age.

The performance is presented in Table 2 below.

Table 2: Summary of the Performance of the BD Veritor System for Rapid Detection of Flu A+B Test Compared to PCR for Retrospective Nasopharyngeal Wash/Aspirate Specimens

	Reference PCR		
Clinical kit: BD Flu A	P	N	Total
P	58	2	60
N	5	184	189
Total	63	186	249
Reference Method: PCR PPA: 92.1% (95% C.I. 82.7%- 96.6%) NPA: 98.9% (95% C.I. 96.2%- 99.7%)			

	Reference PCR		
Clinical kit: BD Flu B	P	N	Total
P	29	2	31
N	10	208	218
Total	39	210	249
Reference Method: PCR PPA: 74.0% (95% C.I. 58.9%- 85.4%) NPA: 99.0% (95% C.I. 96.6%-99.7%)			

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

Becton, Dickinson and Company
c/o Gregory P. Payne, RAC
Director, Quality Systems and Regulatory Affairs
10865 Road to the Cure, Suite 200
San Diego, CA 92121

MAR 2 3 2012

Re: k120049
Trade/Device Name: BD Veritor™ System for Rapid Detection of Flu A + B
Regulation Number: 21 CFR§ 866.3330
Regulation Name: Influenza Serological Reagents
Regulatory Class: Class I
Product Code: GNX
Dated: January 5, 2012
Received: January 6, 2012

Dear Mr. Payne:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter

will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

510(k) Number: k120049

Device Name: BD Veritor™ System for Rapid Detection of Flu A+B

Indications for Use:

The BD Veritor™ System for Rapid Detection of Flu A+B is a rapid chromatographic immunoassay for the direct and qualitative detection of influenza A and B viral nucleoprotein antigens from nasopharyngeal wash/aspirates of symptomatic patients. The BD Veritor System for Rapid Detection of Flu A+B is a differentiated test, such that influenza A viral antigens can be distinguished from influenza B viral antigens from a single processed sample using a single device. The test is to be used as an aid in the diagnosis of influenza A and B viral infections. A negative test is presumptive and it is recommended that these results be confirmed by viral culture or an FDA-cleared influenza A and B molecular assay. Negative test results do not preclude influenza viral infection and should not be used as the sole basis for treatment or other patient management decisions. The test is not intended to detect influenza C antigens.

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Prescription Use √ (Part 21 CFR 801 Subpart D) AND/OR Over-the-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices Evaluation and Safety

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K120049